



United States  
of America

# Congressional Record

PROCEEDINGS AND DEBATES OF THE 110<sup>th</sup> CONGRESS, FIRST SESSION

Vol. 153

WASHINGTON, THURSDAY, AUGUST 2, 2007

No. 126

## Senate

The Senate met at 9:30 a.m. and was called to order by the Honorable DIANNE FEINSTEIN, a Senator from the State of California.

### PRAYER

The Chaplain, Dr. Barry C. Black, offered the following prayer:

Let us pray.

Almighty God, holy, powerful, loving, and good, thank You for Your love expressed in the beauty of the Earth and in the glory of the skies. Use the Members of this body today as instruments of Your providence. Where there is loneliness, let them bring community. Where there is sadness, let them bring joy. Where there is sickness, let them bring health. Where there is poverty, let them bring relief and true wealth. As they seek to serve You, give them the peaceful satisfaction of knowing that they please You. Strengthen them to press on with the work of the day, alert to feel Your hand upon their shoulders.

And, Lord, comfort those who mourn the losses from the bridge collapse in Minnesota.

We pray in Your strong Name. Amen.

### PLEDGE OF ALLEGIANCE

The Honorable DIANNE FEINSTEIN led the Pledge of Allegiance, as follows:

I pledge allegiance to the Flag of the United States of America, and to the Republic for which it stands, one nation under God, indivisible, with liberty and justice for all.

### APPOINTMENT OF ACTING PRESIDENT PRO TEMPORE

The PRESIDING OFFICER. The clerk will please read a communication to the Senate from the President pro tempore (Mr. BYRD).

The legislative clerk read the following letter:

U.S. SENATE,  
PRESIDENT PRO TEMPORE,  
Washington, DC, August 2, 2007.

To the Senate:

Under the provisions of rule I, paragraph 3, of the Standing Rules of the Senate, I hereby appoint the Honorable DIANNE FEINSTEIN, a Senator from the State of California, to perform the duties of the Chair.

ROBERT C. BYRD,  
President pro tempore.

Mrs. FEINSTEIN thereupon assumed the chair as Acting President pro tempore.

### RECOGNITION OF THE MAJORITY LEADER

The ACTING PRESIDENT pro tempore. The majority leader is recognized.

### SCHEDULE

Mr. REID. Madam President, this morning there will be 2 hours of debate on the motion to invoke cloture on the motion to concur in the House amendment to S. 1, the Lobbying and Ethics Reform Act.

The time is to be equally divided and controlled between the leaders or their designees. Following the 2 hours, the leaders will, if they wish, use leader time to conclude the debate. Therefore, the vote on the motion to invoke cloture is expected to occur at around 11:45, or shortly thereafter.

After that cloture vote, we will remain on the lobbying measure until we complete action.

I have spoken to the participants. It appears they are not going to require a lot of time. That should not take much time, so we can get back to work on the matter relating to children's health.

The manager on our side this morning is going to be the distinguished chair of the Rules Committee, Senator FEINSTEIN. She will be first recognized because she is the manager of the bill.

### UNANIMOUS-CONSENT REQUEST— H.R. 2900

Mr. REID. Madam President, I ask unanimous consent that the Senate proceed to the consideration of Calendar No. 270, H.R. 2900, the FDA reauthorization bill; that all after the enacting clause be stricken and Senator KENNEDY's substitute amendment be inserted in lieu thereof; that the bill be read the third time and passed, the motion to reconsider be laid on the table, and the Senate insist on its amendment, request a conference with the House, and that the Chair be authorized to appoint conferees, with the conferees being the members of the HELP Committee.

Further, there were tax measures in this matter that we dealt with on the floor. They have been stricken from the bill. That is what Senator KENNEDY's amendment is all about. I hope we could go to conference on this matter.

The PRESIDING OFFICER (Mr. AKAKA). Is there objection?

Mr. ENZI. Mr. President, reserving the right to object, and before I object, I need to understand the rationale of the majority leader to propound the request at this time. I sent a letter last week. I ask unanimous consent that the letter be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

U.S. SENATE, COMMITTEE ON  
HEALTH, EDUCATION, LABOR, AND  
PENSIONS,

Washington, DC, July 27, 2007.

Hon. HARRY REID,  
Majority Leader, Hart Senate Office Building,  
Washington, DC.

Hon. MITCH MCCONNELL,  
Minority Leader, Russell Senate Office Building,  
Washington, DC.

DEAR SENATOR REID AND SENATOR MCCONNELL: I urge you to appoint conferees as soon as possible to S. 1082, a bill that renews expiring authorities at the Food and Drug Administration (FDA) as well as reforms our drug safety system.

• This "bullet" symbol identifies statements or insertions which are not spoken by a Member of the Senate on the floor.



Printed on recycled paper.

S10685

Every day, we hear about a new problem the FDA faces in protecting our health. From contaminated seafood to tainted toothpaste, this agency is in dire need of Congressional support to carry out its mission. Reauthorizing these programs is critical to ensure that new drugs and medical devices reach the patients who need them.

As you know, this work period is nearly over. If the drug and device user fee programs are not renewed prior to the recess, FDA will have no choice but to send what is known as a "Reduction In Force" or layoff notice to hundreds of FDA employees involved in these programs. These highly skilled and dedicated public servants are not likely to wait until Congress musters enough interest to act to maintain the user fee programs. They will find other jobs. A staff exodus would be a disaster for this agency, and for the public health it safeguards so zealously.

This comprehensive bill will provide new authorities for FDA to be able to react in a timely way to any safety problems that arise after a drug has been brought to market. FDA needs these tools both to get drugs to the market quickly and efficiently and to respond to potential problems the same way, especially when lives are on the line and people need new drugs and therapies.

We must think carefully about our priorities for the limited time we have before the recess begins, and take strong action to give the FDA the resources and tools it needs to protect us. Appointing conferees now would send a powerful message that Congress is working as hard as FDA is to make these programs work.

Sincerely,

MICHAEL B. ENZI,

*Ranking Member, Committee on Health,  
Education, Labor, and Pensions.*

Mr. ENZI. Mr. President, this letter is asking for a conference to be appointed. But it is my understanding the House never intended to appoint one this week. Had I known that, I would not have delivered the letter. We were working in a very bicameral, bipartisan manner on getting this done.

At that time, the key players for this legislation—Representatives, Senators, Republicans, and Democrats—were engaged in a very productive bicameral, and bipartisan preconference negotiation. We had all rolled up our sleeves and decided that we were going to complete the legislation before the August recess.

We had a good core agreement, focused on good policy. That is not to say that there weren't a few sticking points. There always are a few of those, but we were making significant progress and coming to a better understanding of each other's legislation. Thus, the appointment of conferees would have been a simple step in the process.

However, a week later, we are not in the same place. As the majority leader knows, this body can seemingly operate in Senate dog years. One week can be a lifetime. In that short week, there were a series of unfortunate events. These events made it impossible for us to meet the goal of completing this key legislation before August recess. I don't want these unfortunate events to derail this process.

The first unfortunate event was a discussion on the House floor last Fri-

day afternoon between Representative CANTOR and Representative WASSERMAN-SCHULTZ. In that discussion, the House leadership indicated that they did not intend to have the FDA bill on the House suspension calendar this week. Given that I am not one to watch the House floor, I did not realize that this decision had been made by House leadership last Friday. On Monday, that information was conveyed to my staff by the staff of key Democrats engaged in discussion. The House Democrats did not see how this FDA bill was to get done before recess.

Had I known that this was what the House Democrats wanted a few days before, I would not have hand-delivered that letter to the majority leader and the minority leader.

Partially, I believe the decision by House Democrats was related to other items, other priorities facing the House. Like us, the House has been discussing the SCHIP legislation this week. Unlike the Senate, the House committees overlap such that the same committee that works on FDA issues also works on SCHIP issues. While we pride our staff in being able to do the impossible, forcing both FDA and SCHIP at the same time would be well past impossible. Thus, the House Democrats made a choice—SCHIP over FDA.

Partially, I also believe that the House leadership felt as if they could get a "better deal" if they were to wait until September and build up additional pressure related to reduction in force directly related to the reauthorization of the core of the FDA drug safety bill. I hope to disabuse them of that reality.

If we are to answer to the American people, to give FDA the necessary new authorities, we must do this in a bipartisan manner. We should not politicize this. We should not hold out for "better deals" but work together to forge a strong agreement that every American can support.

Therefore, I urge my colleagues not to politicize this issue. Too much is at stake for us to begin the blame game. Instead of blaming each other for potential failure, we should be working to ensure our success. We should be developing a process agreement for how we are to complete this key legislation. We should begin defining the scope of the conference to ensure that extraneous proposals do not weigh down our ability to quickly respond when we return in September.

As part of that first step, I would like everyone to know what I believe is the appropriate scope of the conference. First, we must include the reauthorizations of user fee programs at the FDA to ensure that nearly 2,000 employees at that agency are not laid off. These staff not only ensure that drugs and devices are appropriately and efficiently reviewed before they are allowed to go to market, but they also are in charge of key postmarket safety monitoring of those products. We must reauthorize

the Prescription Drug User Fee Act and the Medical Devices User Fee Modernization Act.

Beyond these items, during our Senate debate on FDA, we discussed key provisions that provided FDA with new authorities to assist the agency in quickly and effectively responding to potential safety issues. These new authorities include requiring labeling changes, requiring postmarket studies to more fully examine potential risks, and to have access to clinical trials information for patients and providers. In addition, we discussed how to address potential conflicts of interest of advisory committee members to ensure greater transparency and preserve scientific integrity. I commend Senator MIKULSKI and Senator GRASSLEY for their work in this area.

In addition, we must include three key provisions that focus on children. The first two—the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act—ensure that drugs used in children are tested on children. The third proposal would increase our ability to have devices geared toward children.

Beyond those, there were a series of other provisions which were key to our bipartisan agreement. There is the Reagan-Udall Foundation provisions to ensure that FDA has additional tools to advance the science behind its regulations. The Senate also debated and then accepted a variety of important provisions related to citizens petitions, direct-to-consumer advertising, counterfeit drugs, and antibiotics and enantiomers.

Senator STABENOW, Senator BROWN, Senator LOTT, Senator THUNE, Senator HATCH and Senator COBURN developed a proposal on citizens petitions that will end the abuse of the system while preserving FDA's ability to review those petitions that have public health merit. Senator ROBERTS and Senator HARKIN worked together successfully to solve the difficult issue of how to see that direct to consumer advertisements provide effective safety information to patients while meeting the stringent test of constitutionality. Senator DORGAN and Senator SNOWE contributed a proposal on counterfeit drugs that will be included here as well. Senator HATCH, Senator BROWN, and Senator BURR developed key public health provisions to ensure access to new antibiotics and drug enantiomers.

Senator BROWN and Senator BROWNBACK offered an important incentive to encourage the development of drugs for tropical diseases. All of these items are important components to this legislation and speak to the larger bipartisan nature of our agreement. Let me say that again. We worked deliberately to ensure that our bill was bipartisan.

Finally, there were a variety of provisions included within the Senate bill to address key food safety provisions. Senator SESSIONS, Senator STEVENS, and Senator DURBIN and I worked on

amendments that addressed issues with food and pet food safety.

While I have discussed several key provisions that have been within the scope of our discussions, we must also discuss what should not be within the scope of this legislation. While a sense of the Senate indicated our desire to make generic biologics—or what I like to call biosimilars—available to American consumers to reduce the costs of some medications while preserving quality, the House has so far made it clear that such legislation would not be welcome on this legislation. They prefer to move through regular order. I understand that desire. I prefer regular order, too.

During our discussion on the Senate floor, there was one provision that I believe put the bill in jeopardy—an importation amendment. The House opted not to include this provision so that they could deal with it at a later date. This bill is not the time for this debate, given that we are focusing on key bipartisan proposals.

So, I turn to the majority leader, and I ask him to refrain from politicizing this issue. I ask him to work with me to define the scope of the conference, to develop a plan for getting this legislation done.

Until the House leadership is in agreement with our plan, we should not force the issue today by appointing conferees too early. If we do this too early, we set ourselves up for the blame game, not for getting this key legislation done. This place should not be about “gotcha” politics when lives are at stake.

Mr. President, I don’t know what the logjam is at the moment. I understand there is some concern on the biologics. There isn’t any reason this cannot be completed, but I am afraid the motion, if we are doing this, would appear to put the blame on the House, or on the Republicans—I am not sure which—and I don’t think we can do that at this point in time. Maybe later in the day.

Mr. REID. Mr. President, if this is the way the Senator feels, I am happy to have him and Senator KENNEDY see if this can be worked out.

I withdraw my unanimous consent request.

#### TRAGEDY IN MINNESOTA

Mr. REID. Mr. President, I wish to make a brief comment on the tragedy in Minneapolis, MN. Watching those pictures on television and listening to the accounts on the radio and seeing newspaper accounts and the pictures, this is a real tragedy. My heart and the hearts of all Americans go out to the people of Minnesota—to those who have died, those who have been injured, and certainly the families and friends of all those people.

I am confident we will find out why that disaster occurred. Right now, we don’t know. There is every reason to believe it was not an act of terrorism. I feel that is the case, based on hearing

the Governor of that State making an announcement this morning.

In passing, I say this. After every storm, the sun shines. I think we should look at this tragedy that occurred and make it a wake-up call for us. All over this country, we have crumbling infrastructure—highways, bridges, and dams. We need to take a hard look at that. We need to look at it as the right thing to do and also not only for the fact that the infrastructure needs repairing or rebuilding, but it is good for America in more ways than that.

For every \$1 billion we spend in our crumbling infrastructure, 47,000 high-paying jobs are created. I hope we will take a look at our highways, bridges, dams, water systems, and sewer systems, and see if we can do something about this infrastructure that needs such attention.

We have some things coming up in the Senate in the near future we need to focus on. This tragedy is a wake-up call. We will have the Transportation appropriations bill, and we will have WRDA, which should be coming from the House. We will have Energy and Water appropriations and other matters. We need to work in a bipartisan way and also to work with the White House and have them realize there are things that need to be done with our country’s infrastructure.

#### RECOGNITION OF THE REPUBLICAN LEADER

The PRESIDING OFFICER. The Republican leader is recognized.

#### TRAGEDY IN MINNEAPOLIS

Mr. MCCONNELL. Mr. President, with regard to the tragedy in Minneapolis, our colleagues, Senators COLEMAN and KLOBUCHAR, are either there or on the way there today to not only extend their condolences to their constituents who have been impacted by this but to be as helpful as possible as they go forward with the rescue mission.

I am reminded of the situation in my State, where the Ohio River goes along the northern border of Kentucky, almost for the entire State, and then when it empties into the Mississippi, it goes southward—the same river over which the Minneapolis bridge collapsed.

We have bridges all along both the Ohio and the Mississippi. Bridge construction and safety has been a big issue in the Commonwealth of Kentucky in recent years.

I share the concerns of the majority leader about reports of the state of our infrastructure in America. We all pray for the victims of the Minneapolis tragedy. It may well serve as a reminder of our need to be ever aware of the dangers that confront our infrastructure in this country.

#### UNANIMOUS CONSENT AGREEMENT—S. 1

Mr. MCCONNELL. Mr. President, with regard to the time allocation on our side during consideration of the lobbying bill, I ask unanimous consent that the time under the control of the Republicans be allocated as follows: Senator COBURN, 10 minutes; Senator DEMINT, 10 minutes; Senator MCCAIN, 10 minutes; Senator GRASSLEY, 5 minutes; and Senator STEVENS, 10 minutes; with the remaining time for myself or my designee.

The PRESIDING OFFICER. Without objection, it is so ordered.

#### THE ABSENCE OF THE SENATORS FROM MINNESOTA

Mr. REID. Mr. President, I should have mentioned this. I appreciate very much my distinguished counterpart mentioning Senator KLOBUCHAR and Senator COLEMAN. I listened to them being interviewed last night on television. You could tell from their presentations how much this meant to them.

AMY KLOBUCHAR’s house is, I think, a mile from where the bridge collapsed. Today, they are where they should be. We have matters in the Senate, and we will certainly miss them. For example, Senator KLOBUCHAR has been heavily involved in this ethics and lobbying reform measure. If there were ever a situation where they should miss votes, this is it.

#### RESERVATION OF LEADER TIME

The PRESIDING OFFICER. Under the previous order, leadership time is reserved.

#### LEGISLATIVE TRANSPARENCY AND ACCOUNTABILITY ACT OF 2007

The PRESIDING OFFICER. Under the previous order, the Senate will resume consideration of the amendment of the House to S. 1, which the clerk will report.

The legislative clerk read as follows:

Message from the House of Representatives to accompany S. 1, entitled “An Act To Provide Greater Transparency in the Legislative Process.”

The PRESIDING OFFICER. Under the previous order, there will now be 2 hours of debate prior to the vote on the motion to invoke cloture on the motion to concur, with the time equally divided and controlled between the two leaders or their designees.

The Senator from California is recognized.

#### TRAGEDY IN MINNESOTA

Mrs. FEINSTEIN. Mr. President, quickly, before I begin, I also wish to send my very deep condolences to those families who will have lost their loved ones in this very tragic bridge collapse. I heard the mayor on the television this morning, and it brought me back to my days as mayor. I know what this